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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,963	01/28/2002	Andras Guttman	1360.038US1	4487
25297	7590	01/29/2004	EXAMINER	
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			STARSIAK, JOHN S	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,963

Applicant(s)

GUTTMAN ET AL

Examiner

John S. Starsiak Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 28 and 29 objected to because of the following informalities: Claims 28 and 29 recite "wherein *creating* a migratory field includes...". However claim 21 upon which these claims depend recites, "*generating* a migratory field". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 to 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites, "interrupting the migratory field after collecting *commences*". This recitation conflicts with several recitations in the written description. For example, page 7, lines 16-18, recite, "Fractions eluted from the separation pathway migrate into the contacted well and when *the separation pathway is moved away from the collection reservoir, the migration is halted.*" Similarly, page 14, lines 13 and 14, recite "In one embodiment, fraction collection occurs while the voltage is applied across the electrode 225." Claim 32 recites, "the method of claim 21 wherein the predetermined time interval is established on a composition of the separation pathway." The meaning of the limitation is incomprehensible, particularly the term "composition of the separation

pathway.” The only occurrence of this term is in claim 32. MPEP 608.01 (o) states: “the meaning of term used in any of the claims should be apparent from the descriptive portion of the specification with a clear disclosure as to its import...”. Claims 22-31 are rejected because they depend on claim 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger et al in view of either Rose & Jorgenson or Burd.

Karger et al. discloses a system for high throughput preparative separation. The methods recited in the claims read on the operation of the system(s) of Karger et al. except for the interruption step recited in claim 21. The “applying a sample” step of claim 21 reads on page 3, lines 5-8” of Karger et al. Although Karger et al. does not explicitly recite the step of “generating a migratory field in the separation pathway”, this step is inherent in the use of system(s) of Karger et al. e.g. an electric field (migratory field) is established the capillaries(separation pathway). The “collecting step” and “repeating step the collection step” of claim 21 read on the following portions of Karger et al. [page 3, lines 8-11 and page 3, lines 20 –25]: “Fractions usually are collected

regardless of the sample composition in fixed time intervals preferably every few seconds, into, e.g., a multi-well plate with a fixed volume (repeated collection step)... Determination of sample separation profile and selection of fractions may also be achieved in a post-process procedure, where collected fractions are scanned in a separate optical device of registering a desired optical characteristic of the collected material" (detection after collection). The eluting step is inherent since the components of the samples separated on the systems of Karger et al. elute (exit) the ends of the capillaries. Hence, the only particular step not explicitly disclosed or inherent in Karger et al is the repeatedly interrupting the migratory field" step. Each of the secondary references teaches interrupting the migratory field during a preparative (collection of separated samples) capillary electrophoretic process. Rose & Jorgenson teaches [last line of page 23 to line 2 of page 24]: "Also the electric field applied during electrophoresis must be interrupted or stopped when moving the capillary from fraction to fraction." Burd teaches [column 4, lines 1-14]: "in the embodiment shown in FIG. 1, it will be noted that the capillary segments 18 are spaced apart at intervals around the cassette 12. The external openings 40 of adjacent capillary segments are separated by portions of the solid external wall 41. In the arrangement shown, these intervening wall portions close of the separation capillary 11 and interrupt the current path whenever the capillary segments 18 are not in alignment between the separation capillary 11 and the outlet buffer reservoir 14. With the current path interrupted in this manner, the electrophoretic migration of the solute species in the separation column 20 as well as all

other portions of the apparatus is momentarily suspended while the cassette rotates further and brings the next capillary segments into position. *Thus, no components of the sample are lost and the entire profile will be distributed among the various capillary segments in the cassette*". Hence, it would have been obvious to one of ordinary skill in the art at the time of the invention that the migratory field (e.g. electric field) of the systems must be interrupted when the capillaries are being transferred to the next set of collection wells, because this step will prevent the loss of a component of the sample during the transfer process. Regarding claim 22, the limitation that the repeated step occur at "substantially uniformly spaced time intervals" reads on the page 13, lines 24-24, of Karger et al., i.e., "During separation, the capillary was moved from one microwell to another in constant time intervals of 30 seconds." Claim 23, reads on page 6, lines 17 and 18, of Karger et al., i.e., "The collection period is determined depending on the desired resolution and speed of the separation", because the resolution and the speed of the separation depend on the mobilities of the components (analytes) in the sample. Regarding claim 24, see the recitation concerning post-process detection above. Claims 25 and 26 read on Karger et al. because the sample in the example of Karger is a "double stranded DNA restriction fragment mixture." The potential recited in claim 28 reads on the electric potential created by the elements of Karger et al. such as electrode (48) and power source (47) of Karger et al. recited on page 9, lines 12 to 15. Regarding the limitations recited in claims 28 and 29, while Karger et al. does not explicitly recite the steps of "creating a migratory field includes applying a pressure

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to the separation pathway” or “creating a migratory field includes drawing a vacuum in the separation pathway” these are considered to be inherent because Karger et al recites [page 5, lines 26-30]: “Any method of separation could be employed, including but not limited to ... *capillary liquid chromatography*...”. In capillary liquid chromatography, fluid flow is the result of a pressure difference being created across the capillary. The limitation of claim 30 is considered to be inherent in the method disclosed by Karger et al. Although Karger et al. does not explicitly recite the step of “positioning the separation pathway relative to the collection well”, it is clear that this step is required to successfully perform the method of Karger et al. In other words, to collect fractions coming out of the capillaries in the wells of the multiwell plate, the capillaries must be “positioned” over the wells. Claim 31 is rejected since reducing the voltage to zero as recited in the secondary references constitutes “adjusting a potential within the separation pathway”. Claim 32 is rejected because the limitation intended by the claim cannot be determined.

Response to Arguments

Applicant's arguments filed 31 October 2003 directed to the rejection of claim 32 based on 35 U.S.C. 112 have been fully considered but they are not persuasive. While the applicant's amendment addressed the first reason for the rejection (lack of recitation of sequential relationship) the applicant's response either by amendment or argument

fails to address the second reason for the rejection (the limitation intended is incomprehensible).

Applicant's arguments with respect to the rejection of claims 21-32 based upon prior art have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John s. Starsiak Jr. whose telephone number is (571)

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272-1346. The examiner can normally be reached on Monday to Friday from 7:30 AM to 4:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1300.


NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700


John S. Starsiak Jr.

20 January 2004